

FEB 17 2012

Arthrex SPECIAL 510(k): Arthrex Knotless SutureTak Anchor

**1 510(k) Summary of Safety and Effectiveness**

<b>Date Summary Prepared</b>	January 17, 2012
<b>Purpose of Submission</b>	To obtain clearance of the <i>Arthrex Knotless SutureTak Anchor</i> devices.
<b>Manufacturer/Distributor /Sponsor</b>	Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA
<b>510(k) Contact</b>	Christina Flores Regulatory Affairs Specialist Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA Telephone: 239/643.5553, ext. 1819 Fax: 239/598.5508 Email: <a href="mailto:christina.flores@arthrex.com">christina.flores@arthrex.com</a>
<b>Trade Name</b>	<i>Knotless SutureTak Anchor</i>
<b>Common Name</b>	fastener, fixation, nondegradable, soft tissue
<b>Product Code - Classification Name</b>	MBI - 21 CFR 888.3040 fastener, fixation, nondegradable, soft tissue HWC - 21 CFR 888.3040: Smooth or threaded metallic bone fixation fastener GAT - 21 CFR 878.5000: Nonabsorbable poly(ethylene terephthalate) surgical suture
<b>Predicate Devices</b>	K061863 <i>Arthrex 3 mm PEEK SutureTak</i>
<b>Device Description and Intended Use</b>	<p>The <i>Arthrex Knotless SutureTak Anchor</i> is a tap-in ribbed suture anchor comprised of PEEK material and preloaded with UHMWPE looped suture and assembled to an insertion device. The proposed anchor is being offered in a 3 mm diameter.</p> <p>The <i>Arthrex Knotless SutureTak Anchor</i> is intended to be used for suture or soft tissue fixation to bone in shoulder, foot/ankle, knee, hand/wrist, elbow, and hip. These indications are identical to those cleared in K061863 with the exception of the removal of the Skull and Pelvis indications.</p> <p>The Arthrex Knotless SutureTak Anchor is intended to be used for suture or tissue fixation in the foot, ankle, knee, hand, wrist, elbow, shoulder, and hip. Specific indications are listed below:</p> <p><i>Elbow:</i> Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction</p> <p><i>Shoulder:</i> Rotator Cuff Repairs, Bankart Repair, SLAP</p>

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	<p>Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction</p> <p><i>Hand/Wrist:</i> Scapholunate Ligament Reconstruction, Carpal Ligament Reconstructions, Repair/Reconstruction of collateral ligaments, Repair of Flexor and Extensor Tendons at the PIP, DIP, and MCP joints for all digits, Digital Tendon Transfers</p> <p><i>Foot/Ankle:</i> Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Metatarsal Ligament Repair, Hallux Valgus reconstruction, Digital Tendon Transfers, Mid-foot Reconstruction</p> <p><i>Knee:</i> Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis</p> <p><i>Hip:</i> Capsular Repair, Acetabular Labral repair</p>
<b>Substantial Equivalence Summary</b>	<p>The <i>Arthrex Knotless SutureTak Anchor</i> is substantially equivalent to the predicate devices in which the basic features and intended uses are the same. Any differences between the <i>Knotless SutureTak Anchor</i> and the predicates are considered minor and do not raise questions concerning safety and effectiveness.</p> <p>The mechanical testing demonstrates that the proposed device meets or exceeds the established minimum acceptance criteria for tensile (pull-out) strength for the desired indications.</p> <p>Based on the indication for use, technological characteristics, and summary of data submitted, Arthrex, Inc. has determined that the <i>Arthrex Knotless SutureTak Anchor</i> is substantially equivalent to currently marketed predicate devices.</p>



DEPARTMENT OF HEALTH & HUMAN SERVICES

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FEB 17 2012

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Mail Center - WO66-G609  
Silver Spring, MD 20993-0002

Arthrex, Inc.  
% Ms. Christina Flores  
1370 Creekside Boulevard  
Naples, FL 34108-1945

Re: K120155  
Trade/Device Name: Arthrex Knotless SutureTak Anchor  
Regulation Number: 21 CFR 888.3040  
Regulation Name: Smooth or threaded metallic bone fixation fastener  
Regulatory Class: II  
Product Code: MBI, HWC, GAT  
Dated: January 17<sup>th</sup>, 2012  
Received: January 18<sup>th</sup>, 2012

Dear Ms. Flores:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



*for* Mark N. Melkerson  
Director  
Division of Surgical, Orthopedic  
and Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

### 3 Indications for Use Form

#### Indications for Use

510(k) Number (if known): K120155

Device Name: Arthrex Knotless SutureTak Anchor

#### Indications For Use:

The Arthrex Knotless SutureTak Anchor is intended to be used for suture or tissue fixation in the foot, ankle, knee, hand, wrist, elbow, shoulder, and hip. Specific indications are listed below:

<i>Elbow:</i>	Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction
<i>Shoulder:</i>	Rotator Cuff Repairs, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction
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<i>Hip:</i>	Capsular Repair, Acetabular Labral repair

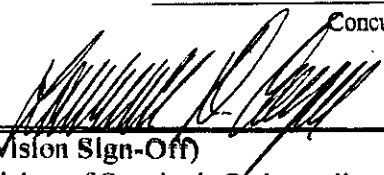
Prescription Use ☒ AND/OR Over-The-Counter Use \_\_\_\_\_

(Per 21 CFR 801 Subpart D)

(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)

Division of Surgical, Orthopedic,  
and Restorative Devices

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